

Participant Informed Consent Form

Dear patient:

We look forward to inviting you to participate our clinical trail study. In order to ensure that our study process goes well, and guarantee your rights and interests. We wish you read following information carefully before you agree to take part.

Basic information about clinical trail study:

Title of Study:

A Multicenter Randomized Controlled Trail of Vitamin K1 in the treatment of Spontaneous Intracerebral Hemorrhage.

Investigator:

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Sponsor:

The study is funded by Shenzhen Second People's Hospital, Guangdong province, China.

What is the study about?

Introduction of Vitamin K1:

Vitamin K1 is essential for synthesizing prothrombin in liver, coagulopathy occurs when deficiency present. When prothrombin deficiency is present in the blood, blood coagulation will be sluggish. At this time, supplementing appropriate amount vitamin K1 can promote the synthesis of prothrombin in liver, which play a role in hemostasis. Vitamin K1 as one of the pharmaceutical preparation, which clinical application in the prevention and treatment of hypoprothrombinemias., vitamin K1 deficiency and neonatal spontaneous hemorrhage, bleeding due to obstructive jaundice, biliary fistula chronic diarrhea, and coumarin, sodium salicylate and so on cause hypoprothrombinemias. Vitamin K1 has the effect of analgesic, relieve bronchospasm, it is also has obvious effect of colicky pain due to visceral smooth muscle angina, spasm of biliary ducts, enterospasm.

Indications of Vitamin K1:

1. Hypoprothrombinemia: intramuscular or deep subcutaneous injection of 10 mg per time, 1-2 times per day, and no more than 40mg in 24 hours.
2. Prevention of neonatal haemorrhage: intramuscular or slow intravenous injection of 2-5mg was given 12 to 24 hours before delivery. Also can intramuscular or subcutaneous injection of 0.5-1 mg to neonate after birth, then repeat after 8 hours.
3. Intravenous injection vitamin K1 should not exceed 1mg/min when used for patients with severe diseases.
4. Vitamin K1 can be used for chronic poisoning caused by brodifacoum. Specific usage: (1) iv injection of 5 mg/kg, 2 to 3 times as needed, each time interval 8-12 hours. (2) oral 5 mg/kg for 10-15 days. (3) transfuse 200 ml acidifying blood.

Purpose of the study:

The study mainly research on the possibility of using vitamin K1 to reduce hemorrhage in patients with spontaneous intracerebral hemorrhage. Most cerebral hemorrhage related to prognosis directly, reducing cerebral hemorrhage can improve the prognosis of patients, decrease the hospital day and admission ICU time, also decrease the mortality.

Do I meet the standards of participation?

Recruit criteria:

1. Spontaneous cerebral hemorrhage, non-aneurysm rupture cerebral hemorrhage (conventional CTA);
2. Male, and unpregnancy women aged 18-65;
3. GCS score on hospital admission (4-12 points);
- 4 The head CT scan confirmed that the intracerebral hemorrhage was supratentorial, and not broken into the cerebral ventricle between 10-45ml (Coniglobus formula) ;
5. Patients or family members have signed informed consent ;
6. CT or MRI confirmed the bleeding on the clear screen;
8. Urokinase was not used;
9. Hemostatic drugs are not used.

Exclusive criteria:

1. The CT scan of hematoma was irregular, such as meniscus, lobes, long strips and bleeding into the ventricle (because there was no accurate measurement of blood loss);
2. Severe liver disease or hepatic functional lesion are prohibited;
3. Pregnant or lactating women;
4. Oral or injection of anticoagulant drugs (aspirin, cilostazol, dipyridamole), excluding oral antiplatelet aggregation drugs (heparin, hirudin, dabigatran, legislative shaaban, warfarin);
5. Unsigned informed consent;
6. After admission, the blood pressure should not be controlled within 2 hours at 150/100mmHg;
7. GCS 3 points, double pupil loose large fixed or Anautonomic respiration.

The inclusion criteria were randomly divided into the experimental group and the control group.

What will happen in the study:

The experimental group: 2 days after hospital admission, patients received 0.9%NaCl 100ml+Vitamin K1 20mg(102ml totally) intravenously during 1 hour per day.

The control group: 2 days after hospital admission, patients received 0.9%NaCl 102ml intravenously during 1 hour per day.

How long will I be in the study?

Your part in the study will last 6 months and 2 days. (2 days for medication,6 months for follow-up.)

What if I have questions?

You can contact our investigators at working time if you have questions about the study. Dr.Xianjian Huang is in charge of the study. You may also contact Dr. Xianjian Huang at working time if you have questions about the study.

Do I have to be in the study?

You decide if you want to be in the study. Deciding not to take part will not affect your relationship with your medical provider .If your health care provider is an investigator for the study, you may get a second opinion from another doctor not involved in the study.

You can leave the study at any time and you do not have to give a reason. Leaving the study will not affect your relationship with your medical provider.

The study investigators may ask you to leave the study if it is in your best interest. The study investigator may ask you to leave the study if you do not follow the study rules.

What if I don't want to be in the study?

You can choose not to be in the study and you do not have to give a reason. You can choose to talk to their doctor about other options or investigate outside resources on their own.

Are there any costs?

All study-related treatments are free.

Will I be paid for being in the study?

You will not be paid for being in the study.

Are there any risks?

There is always a small risk of a breach of confidentiality to your personal health information. Occasional hypersensitivity reaction,severe allergic reactions can endanger life.And if intravenous injection too fast, over 5mg/min can cause facial flushing, sweating, bronchospasm, tachycardia, hypotension,etc.Intramuscular injection can cause local redness,swelling and pain.However, these risks will be addressed and minimized as much as possible.

You will be told about any new information that may affect your willingness to participate in the study.

There could be risks that we are unaware of at the time of the study.

Are there any benefits?

It is possible you may receive some benefit from using vitamin K1, such as decreasing cerebral hemorrhage, improving prognosis, decrease hospital day, etc. There is no guarantee, however, that you will receive any benefit at all. Your participation will help us learn more about the therapeutic effect of vitamin K1 reducing cerebral hemorrhage in spontaneous intracerebral hemorrhage.

Your privacy is important

Protecting your privacy is very important to us.

During this study we will ask about your past and current medical history, we will do this with questionnaires, medical exams, blood draws, etc. This information will be used to determine your eligibility for the study and provide data for the study. Your personal health information will be kept private and only authorized study staff will have access to this information. We will use a study number instead of your name. All paper forms will be kept in a locked, secure office. All electronic data will be stored on password-protected computers. Your name will not be used in any publications or presentations about this study.

During the study, you may not be given access to medical information about you that is part of the study. When the study is over, you may request certain medical information collected about you that is part of your study medical record.

By signing this consent form you are stating that we can use your health information in the ways mentioned above for this study. You are not waiving any of your legal rights by signing this form.

You have the right to take away your permission to use your health information and any blood and/or tissue samples collected as part of the study. In order to do this you must contact our investigators.

If you take away your permission to use your tissue or blood samples for a genetics research study, your samples will be destroyed or stored without any information that identifies you.

We are collecting only the personal health information that we need for the specific purpose of this study. Your personal health information cannot be used for additional research purposes.

If your personal health information is disclosed by this authorization to an individual or agency not covered by laws that prohibit re-disclosure, your personal health information may not remain confidential.

Your permission to use your identifiable health information will expire when the study is complete.

Signatures:

By signing this consent form it means the following:

- I know my rights have not been waived by signing.
- I have had all of my questions answered and I know whom to ask if I have more questions.
- I have read this form and understand it.
- I want to join the study.
- I know I can leave the study at any time and do not have to give a reason.

Signature of Participant

Date

Printed name of participant

(If appropriate, signature and printed name of parent or legal guardian with date.)

Thank you for participating in our research study!